

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<p style="text-align: center;">C 1 P L NOV 10 2003 INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i></p> <p>Sheets Enclosed 1 of 1</p>				<b>Complete if Known</b>	
				<b>Application Number</b>	10/628,957
				<b>Filing Date</b>	07/28/2003
				<b>First Named Inventor</b>	Marc. R. Montminy
				<b>Group Art Unit</b>	
				<b>Examiner Name</b>	
				<b>Attorney Docket Number</b>	SALK1650-6 (088802-2758)

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
32	A1	International Search Report for application PCT/US95/01325.	
32	A2	Chirvia et al., "Phosphorylated CREB binds specifically to the nuclear protein CBP." Nature, 365:855-859, 1993.	
32	A3	Lee and Masson, "Transcriptional regulation by CREB and its relatives." Biochimica et Biophysica Acta, 1174:221-233, 1993.	
32	A4	Masson et al., "Identification of proteins that interact with CREB during differentiation of F9 embryonal carcinoma cells." Nucleic Acid Research, 21(5): 1163-1169, 1993.	

Examiner Signature

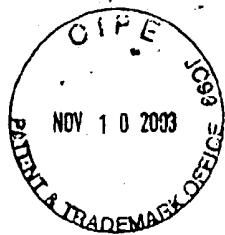
Date Considered

11/11/04

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



Atty. Dkt. No. SALK1650-6  
(088802-2758)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Marc. R. Montminy

Title: METHODS FOR TREATING  
DIABETES MELLITUS

Appl. No.: 10/628,957

Filing Date: 07/28/2003

Examiner:

Art Unit:

<b>CERTIFICATE OF MAILING</b>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.	
<u>DIANE GARCIA</u> (Printed Name)	
<u>Diane Garcia</u> (Signature)	
11-6-03 (Date of Deposit)	

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicant submits herewith a listing of the documents cited by or submitted to the U.S. PTO in related application Serial Nos. 08/961,739; 09/515,276; and 09/686,316, filed 10/31/1997; 02/29/2000; and 10/10/2000 respectfully. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

Also submitted herewith on a form PTO-SB08 is a listing of documents cited in the International Search Report for related international application PCT/US95/01325. Copies of the documents cited in the search report are being provided herewith.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

Atty. Dkt. No. SALK1650-6  
(088802-2758)

§1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of all forms be returned in accordance with MPEP §609.

Atty. Dkt. No. SALK1650-6  
(088802-2758)

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date November 6, 2003

By Barry Wilson

FOLEY & LARDNER  
Customer Number: 30542  
Telephone: (858) 847-6722  
Facsimile: (858) 792-6773

Barry S. Wilson  
Attorney for Applicant  
Registration No. 39,431

FORM PTO 1449 US Department of Commerce Patent and Trademark Office		ATTY DOCKET NO.: SALK1650-1	SERIAL NO.: 08/961,739
		APPLICANT(S): Marc. R. Montminy	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: Oct. 31, 1997	GROUP ART UNIT: N/A

#### U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
		NONE					

#### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
		NONE					

#### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

32	Alberts et al., "Protein Phosphatase 2A Potentiates Activity of Promoters Containing AP-1-Binding Elements" in <i>Mol. and Cell Biol.</i> 13:2104-2112 (1993)
BOOK 32	Ausubel et al., <i>Current Protocols in Molecular Biology</i> (Greene Publishing Associates, Inc. and John Wiley & Sons, Inc. 1993)
32	Boyle et al., "Activation of Protein Kinase C Decreases Phosphorylation of c-Jun at Sites That Negatively Regulate Its DNA-Binding Activity" in <i>Cell</i> 64:573-584 (1991)
32	Chrivia et al., "Phosphorylated CREB binds specifically to the nuclear protein CBP" in <i>Nature</i> 365:855-859 (1993)
BOOK 32	Deutscher et al., <i>Guide to Protein Purification: Methods in Enzymology</i> Vol. 182, (Academic Press, 1990)
32	Gonzalez et al., "Characterization of Motifs Which Are Critical for Activity of the Cyclic AMP-Responsive Transcription Factor CREB" in <i>Mol. and Cell Biol.</i> 11(3):1306-1312 (1991)
32	Hagiwara et al., "Transcriptional Attenuation Following cAMP Induction Requires PP-1-Mediated Dephosphorylation of CREB" <i>Cell</i> 70:105-113 (1992)

EXAMINER <i>32</i>	DATE CONSIDERED 11/11/04
-----------------------	-----------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449	US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.:	SERIAL NO.:
		SALK1650-1	08/961,739
		APPLICANT(S):	Marc. R. Montminy
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: Oct. 31, 1997	GROUP ART UNIT: N/A

BOOK <i>32</i>	Harlow and Lane, <i>Antibodies: A Laboratory Manual</i> (Cold Spring Harbor Laboratory 1988)
<i>32</i>	Hibi et al., "Identification of an oncoprotein-and UV-responsive protein kinase that binds and potentiates the c-Jun activation domain" in <i>Genes and Develop.</i> 7:2135-2148 (1993)
<i>32</i>	Hill et al., "Functional Analysis of a Growth Factor-Responsive Transcription Factor Complex" in <i>Cell</i> 73:395-406 (1993)
<i>32</i>	Hollenberg and Evans, "Multiple and Cooperative <i>Trans</i> -Activation Domains of the Human Glucocorticoid Receptor" in <i>Cell</i> 55:899-906 (1988)
<i>32</i>	Keegan et al., "Separation of DNA Binding from the Transcription-Activating Function of a Eukaryotic Regulatory Protein" <i>Science</i> 231:699-704 (1986)
<i>32</i>	Leonard et al., "Characterization of Somatostatin Transactivating Factor-1, a Novel Homeobox Factor That Stimulates Somatostatin Expression in Pancreatic Islet Cells" in <i>Mol. Endocr.</i> 7: 1275-1283 (1993)
<i>32</i>	Nakajima et al., "Analysis of a cAMP-responsive activator reveals a two-component mechanism for transcriptional induction via signal-dependent factors" <i>Genes Dev</i> (1997) 11(6):738-747
<i>32</i>	Parker et al., "Phosphorylation of CREB at Ser-133 Induces Complex Formation with CREB-Binding Protein via a Direct Mechanism" <i>Mol Cell Biol</i> (1996) 16(2):694-703
<i>32</i>	Smeal et al., "Oncogenic and transcriptional cooperation with Ha-Ras requires phosphorylation of c-Jun on serines 63 and 73" in <i>Nature</i> 354:494-496 (1991)
<i>32</i>	Webster et al., "The Hormone-Binding Domains of the Estrogen and Glucocorticoid Receptors Contain an Inducible Transcription Activation Function" in <i>Cell</i> 54:199-207 (1988)
<i>32</i>	Webster et al., "The Yeast UAS <sub>G</sub> Is a Transcriptional Enhancer in Human HeLa Cells in the Presence of the GAL4 <i>Trans</i> -Activator" in <i>Cell</i> 52:169-178 (1988)

EXAMINER <i>Zar</i>	DATE CONSIDERED <i>11/10/9</i>
------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

2752

PTO 892 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			SERIAL NUMBER 08/961739	Art Unit 1643	Attachment to Paper Number 5		
NOTICE OF REFERENCES CITED			Applicant(s): Montminy				
U.S. PATENT DOCUMENTS							
*	DOCUMENT NUMBER	DATE	NAME(S)	CLASS	SUBCLASS	FILING DATE	
*	6,750,338	5/1998	Montminy	435	0	2/1994	
FOREIGN PATENT DOCUMENTS							
*	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	PERTINENT DRW SPEC
OTHER REFERENCES (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
	Montminy et al., Regulation of somatostatin gene transcription by cyclic adenosine monophosphate, Metabolism 45 (8 Suppl 1):4-7, Aug. 1996.						
EXAMINER  D. Wortman		DATE 9/17/98	A COPY OF THIS REFERENCE IS NOT BEING FURNISHED WITH THIS OFFICE ACTION. (SEE MPEP SECTION 707.05(a)).				
PAGE 1 OF 1							

11/11/04

**Notice of References Cited**Application/Control No.  
09/515,276Applicant(s)/Patent Under  
Reexamination  
MONTMINY, MARC R.Examiner  
Donna C. Wortman, Ph.D.Art Unit  
1648

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,750,336	05-1998	Montminy	435/6
*	B	US-6,063,583	05-2000	Montminy	435/7.21
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	Mayr, B. et al. "Transcriptional Regulation by the Phosphorylation-Dependent Factor CREB" Nature Reviews, Vol 2, (August 2001), pp. 599-609.
*	V	Herzig, S. et al. "CREB regulates hepatic gluconeogenesis through the coactivator PGC-1" Nature, Vol. 413, September 2001 pp. 179-183.
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

*Examiner*

PTO 892 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			SERIAL NUMBER 09/515276	Art Unit 1648	Attachment to Paper Number 6		
NOTICE OF REFERENCES CITED							
Applicant(s): Montminy							
U.S. PATENT DOCUMENTS							
*	DOCUMENT NUMBER	DATE	NAME(S)	CLASS	SUBCLASS	FILING DATE	
FOREIGN PATENT DOCUMENTS							
*	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	PERTINENT DRW SPEC
OTHER REFERENCES (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
<i>32</i>	The Merck Manual, Seventeenth Edition, pages 169-177. Merck Research Laboratories, Whitehouse Station, N.J., 1999.						
EXAMINER <i>-D. Wertman</i>	DATE 6/27/1	' A COPY OF THIS REFERENCE IS NOT BEING FURNISHED WITH THIS OFFICE ACTION. (SEE MPEP SECTION 707.05(a)).					
PAGE 1 OF 1							

*Yurin*

*11/11/04*

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			SERIAL NUMBER 08/961739 09/515276	Art Unit 1643	Attachment to Paper Number 8			
NOTICE OF REFERENCES CITED			Applicant(s): Montminy					
U.S. PATENT DOCUMENTS								
*		DOCUMENT NUMBER	DATE	NAME(S)	CLASS	SUBCLASS	FILING DATE	
		5,582,995	12/1996	Avruch et al.	435	71	6/1993	
		5,705,342	1/1998	Bischoff et al.	435	6	6/1995	
FOREIGN PATENT DOCUMENTS								
*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	PERTINENT DRW SPEC
OTHER REFERENCES (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)								
EXAMINER D. Wortman		DATE 4/15/99	A COPY OF THIS REFERENCE IS NOT BEING FURNISHED WITH THIS OFFICE ACTION. (SEE MPEP SECTION 707.05(a)).					
PAGE 1 OF 1								

*3m*

*11/10/99*

2754

<b>Notice of References Cited</b>	Application/Control No.	Applicant(s)/Patent Under Reexamination	
	09/686,316	MONTMINY, MARC R.	
Examiner	Donna C. Wortman, Ph.D.	Art Unit 1648	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-			
B	US-			
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N	WO 90/05745	05-1990	PCT	Habener et al.	—
O					
P					
Q					
R					
S					
T					

**NON-PATENT DOCUMENTS**

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)	
U		
V		
W		
X		

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

3000 2000

11/11/04

<b>Notice of References Cited</b>	Application/Control No.	Applicant(s)/Patent Under Reexamination	
	09/686,316	MONTMINY, MARC R.	
Examiner	Art Unit	Donna C. Wortman, Ph.D.	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-			
B	US-			
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
R					
S					
T					

**NON-PATENT DOCUMENTS**

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)	
U	Sheng et al., CREB: A Ca <sup>2+</sup> -Regulated Transcription Factor Phosphorylated by Calmodulin-Dependent Kinases. Science 252:1427-1430, 1991.	
V		
W		
X		

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.